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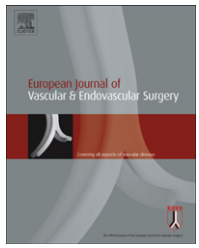

Inframalleolar Bypass Grafts for Limb Salvage

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KEYWORDS
Critical limb ischaemia;
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Plantar artery;
Limb salvage

Abstract *Objective:* To report our experience of long-term results of inframalleolar bypass.
Design: Retrospective analysis.
Materials and methods: We analysed 122 inframalleolar bypasses performed between January 1991 and June 2005 in 116 patients. Most patients were treated for critical ischaemia (97%). The indication for the use of podalic arteries was a lack of tibial arteries with run-off to the foot. The dorsalis pedis was predominantly used for distal anastomoses (62.3%) and the greater saphenous vein (84.4%) as the conduit. The follow-up periods ranged from 1 to 60 months. The endpoints analysed were graft patency, limb salvage, preservation of deambulation and survival rate.
Results: The cumulative patency was 58.2% at 3 years and 53.4% at 5 years. The best results were achieved with the devalvulated greater saphenous veins. Limb salvage was 70.0% at 3 years and 50.4% at 5 years, with preserved deambulation rates of 57.3% and 47.1%, respectively. There were 36 major and 45 minor amputations. At 3 years, the survival rate was 50.2% and the surgical mortality 13%. Female sex was associated with worse results for cumulative patency and limb salvage ($P < 0.01$).
Conclusions: In the long term, inframalleolar bypass is a satisfactory option for limb salvage.

Introduction

In 1959, Morris[1] described the first anastomosis to the distal popliteal artery. Since then, several reports have demonstrated the success of this type of bypass in the treatment of critical limb ischaemia (CLI).[2] McCaughan[3] reported favourable results with the revascularisation of leg arteries using autogenous veins and composite grafts. Later, McCaughan,[4] Harjola[5] and Baird[6] reported good results with saphenous vein bypass grafts to the ankle and foot arteries.

Most patients with CLI, especially those with diabetes, show extensive occlusion of the leg arteries with preservation of the foot arteries, on angiographic examination. Good clinical results have been obtained with podalic bypasses in these patients as reported by several groups.[7–10]

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In 2003, Pomposelli et al.[11] reported a large series in a 10-year study of bypasses to the dorsalis pedis artery, which produced good results for limb salvage.

Recently, percutaneous transluminal angioplasty (PTA) has been considered a feasible revascularisation method. However, the outcomes of tibial PTA are difficult to predict from the existing literature, because few details are given of the intervention indications and lesion characteristics.

The objective of this report was to relate our experience with inframalleolar bypass as an option for limb salvage, with emphasis on the medium- and long-term results of this procedure.

Materials and methods

We conducted a retrospective analysis of 122 inframalleolar bypasses performed in 116 patients between January 1991 and June 2005 in the Hospital do Servidor Público Estadual de São Paulo, in the city of Sao Paulo, Brazil. The data were collected from the medical records of these patients.

We analysed the surgical indications, demographic data, associated co-morbidities, surgical procedures performed and outcomes after surgery and discharge. The main endpoints analysed were graft patency, limb salvage, preservation of deambulation and survival rates. All the patients were treated for CLI (rest pain, non-healing ulcerations or gangrene) and presented with extensive atherosclerotic disease of the leg arteries but preservation of the foot arteries. Since 2001, all patients have been classified according to the TransAtlantic InterSociety Consensus (TASC) classification. The majority of indications were extensive arterial disease of the leg arteries (TASC C or D; Fig. 1); patients classified as TASC A or B were preferentially treated with an angioplasty method. Unfortunately, angiographies performed before 2001 were not available for analysis, so we cannot report the relevant TASC classifications.

After discharge, graft patency was determined by a physical examination that included palpation of the graft and assessment of the ankle—brachial index (ABI), performed either at the hospital's clinic or at the patient's home. Since 1998, duplex scanning has been used for bypass surveillance; when this method or physical examination showed any abnormality, arteriography was performed. Since 2001, bypass surveillance has been conducted in accordance with TASC.[12]

The medications prescribed after surgery included antiplaquetary drugs (aspirin 100 mg day^{-1} or ticlopidine 500 mg day^{-1}) and more recently, statins (simvastatin 20 mg day^{-1}). The wounds were usually treated topically with 1% silver sulfadiazine because it is cheap and highly effective. Most patients were examined with angiography before the surgical bypass, but post-1998, we began to use duplex map scanning as the diagnostic method in patients with limitation in use of contrast. This procedure was used in seven patients (6%).

Grafts were considered long when the inflow originated from arteries above the knee, and short when they originated from arteries below it. Loupe magnification was used for dissection and vessel anastomosis.

The statistical analysis was performed with SPSS 13.0 software (LEAD Technologies Inc.). Independent variables were assumed to be significant if the *P* value was less than 0.05. Survival rates were calculated with a cumulative life table (Kaplan—Meier) with a standard error (SE) of less than 10%. The Mantel—Cox log-rank test was used to compare the survival curves of different groups.

Figure 1 Angiography — extensive atherosclerotic disease of leg arteries (TASC D).

Follow-ups and statistical analysis were performed in accordance with TASC.[12]

This study was approved by the hospital's ethics committee.

Results

The follow-up periods ranged from 1 to 60 months, with a mean length of 25 months.

There was a predominance of males (78 men and 38 women), the mean age was 67 years (range 33—86), and the main associated disease was diabetes mellitus (84%). Other risk factors and associated diseases are shown in Table 1.

Surgery was indicated for CLI in 97% of patients and for previous graft salvage in 3% (Table 2).

Primary patency was 51.4% after 3 years and 46.7% after 5 years. During this period, we performed 13 revisions of these grafts, with a secondary patency of 58.2% (3 years) and 53.4% (5 years; Graphic 1). Fifty-four occlusions occurred in the 3-year period and 55 in the 5-year period.

Table 1 Demographics characteristic.

Demographics	Number of patients
Age (mean; years)	67.26 ± 10.19
Male gender	78 (67%)
Diabetes mellitus	103 (84%)
Hypertension	88 (72.1%)
Current smoker	39 (32%)
Coronary artery disease	16 (13.2%)
Congestive heart failure	16 (13.2%)
Kidney failure	11 (9%)

Autologous veins were used in all reconstructions. When the greater saphenous vein was unusable or had been used previously, we preferentially used arm veins. When these were not available, we used the lesser saphenous vein; in these situations, the use of composite grafts was common. The conduits are summarised in Table 3. At 3 years, we compared the cumulative patency of bypasses made with saphenous veins and those made with alternative grafts. The cumulative patency was 60.4% for saphenous veins and 37.9% for the alternative grafts, but the SE was higher than 10%.

We preferentially used non-reversed, removed devalvulated veins (74 cases, 60.6%), but used reversed veins in 28 patients (22.9%) and *in situ* bypass in one patient. At 3 years, the cumulative patency in the patients treated with reversed veins was 60%, whereas in those treated with removed devalvulated veins, cumulative patency was 61.6% ($P = 0.8$).

The most common distal bypass performed was below-knee popliteal artery to dorsalis pedis artery (13 patients). The long- and short-graft origin sites and distal anastomoses are summarised in Table 4. For the long grafts ($n = 46$) (Fig. 2), the cumulative patency at 5 years was 55.5%; for the short grafts ($n = 76$; Fig. 3), it was 51%. These results are not significantly different ($P = 0.87$; SE $< 10\%$).

The preoperative ABI was calculated for 90 of 122 limbs; the mean ABI was 0.47. In 13 patients (10.7%), the ABI was higher than 1.0, which was attributed to calcified arteries; consequently, these were not considered.

We analysed 21 bypasses to the vicariate branches of the foot arteries (medial plantar in 13 patients, lateral plantar in three and tarsal lateral in 5 patients). These bypasses had a cumulative patency of 39.6% and a limb salvage rate of 77% at 3 years but the SE was acceptable for only six months.

In the 116 patients, 36 major amputations were performed (30 below the knee and 6 above the knee) and 45 minor amputations, which did not exceed the metatarsal level. Limb salvage was 70.0% at 3 years and 50.4% at 5 years, preserved deambulation was 57.3% and 47.1%, respectively (Graphic 1).

Table 2 Indications for surgery.

Indications	Number of patients
Gangrene	68 (55.7%)
Infection	27 (22.1%)
Non-healing ulcer	17 (13.9%)
Rest pain	6 (4.9%)
Bypass salvage	4 (3.3%)

Table 3 Autologous veins conduits.

Conduits	Number
Greater saphenous non-reversed removed and devalvulated	74 (60.6%)
Greater saphenous reversed	28 (22.9%)
Greater saphenous in-situ	1 (0.8%)
Cephalic vein	5 (4.1%)
Basilic vein	2 (1.6%)
Lesser saphenous	2 (1.6%)
Composite grafts	10 (8.2%)

In 122 operations, there were three (2.4%) graft infections, which were treated with re-intervention and graft ligature, followed by major amputation. In all these cases, multi-drug-resistant *Staphylococcus aureus* was isolated and treated with an appropriate antibiotic, but without success.

Univariate analysis of the demographic and clinical factors showed that females were associated with worse results for cumulative patency and limb salvage (Graphic 2; Table 5). We also compared the results of bypasses in diabetic and non-diabetic patients; no statistical significance was found in terms of cumulative patency and limb salvage, but analysis of cumulative patency showed an SE of less than 10% in the non-diabetic group ($n = 19$) only until the second month (Graphic 3; Table 5).

The patient survival rates were 50.2% at 3 years and 38.4% at 5 years. Surgical mortality was 13% (16 patients).

The follow-up rate for patients after hospital discharge was 71.7%, including ambulatory and home visits.

Discussion

It has been demonstrated in several studies[13–15] that bypasses to inframalleolar vessels are effective in limb salvage. We examined our experience of several factors that influence the patency of these bypasses. The frequency of diabetic patients (84%) in our series was high. This has previously been noted by Strandness[16] as a factor associated with the greater preservation of foot arteries than the tibial ones.

In the present analysis of patients after 3 years, only the female sex predicted worse results for cumulative patency (33.8% vs. 68.4% in males; $P < 0.001$) and limb salvage (57.1% vs. 77.2% in males; $P = 0.005$). This finding has already been reported and related to the presence of anti-phospholipid antibodies, which occur more frequently in females and are associated with the failure of bypass grafts.[17] Our study was a retrospective analysis and the identification of anti-phospholipid antibodies was not the purpose of this analysis.

Preoperative angiography is important in the study of leg and foot arteries, and we preferentially use digital angiography with non-ionic contrast injected into the femoral artery. Our second option as a diagnostic method is arterial duplex scan mapping in patients in whom the use of contrast is restricted. The dorsalis pedis artery is usually the best-preserved artery in the foot, so it is the most common site of distal anastomosis.[11,12] We used this artery in 76 (62.3%) patients.

Table 4 Inflow arteries and distal anastomoses.

Inflow arteries		Number
Long bypass	Common femoral	8 (6.6%)
	Superficial femoral	26 (21.3%)
	Above-knee popliteal	11 (9.0%)
	Previous graft	7 (5.7%)
Short bypass	Below-knee popliteal	52 (42.6%)
	Tibial-peroneal trunk	1 (0.8%)
	Anterior tibial	10 (8.2%)
	Posterior tibial	7 (5.7%)
Distal anastomosis	Dorsalis pedis	76 (62.3%)
	Common plantar	25 (20.5%)
	Medial plantar	13 (10.1%)
	Lateral tarsica	5 (4.1%)
	Lateral plantar	3 (2.5%)

A controversial issue debated in the literature is the choice of a distal graft anastomosis when the leg and foot arteries are preserved. Bergamini et al.[18] prefer to use the artery in the best condition for implantation, but this will also depend on the extent of the trophic lesions and the condition of the skin at the site of the incision. Pedal arteries are situated at a superficial level, which makes a distal anastomosis easier, and there is no difference between using a leg or a foot artery for a distal anastomosis when the trophic lesions are stable.[19] When tissue necrosis is worsening, it is better to use a foot artery as the target vessel to achieve a direct pulsating blood flow.

When wet gangrene or a plantar abscess is present, antibiotics must be administered and all the necrotic tissues removed before the bypass. In superficial and dry necrosis, debridement can be performed after revascularisation.

Some patients, especially those with diabetes, may present with rest pain or gangrene of the foot, even with an ABI greater than 0.5. In these cases, inframalleolar revascularisation could be necessary for limb salvage. This situation was observed in 48 (53%) of the present patients.

The use of a reversed or non-reversed vein for the bypass is a contentious issue. When the surgical team is expert in both techniques, the results are similar.[20,21] However, we should also consider the relative vein and artery diameters. In long bypasses, we prefer to use non-reversed removed and

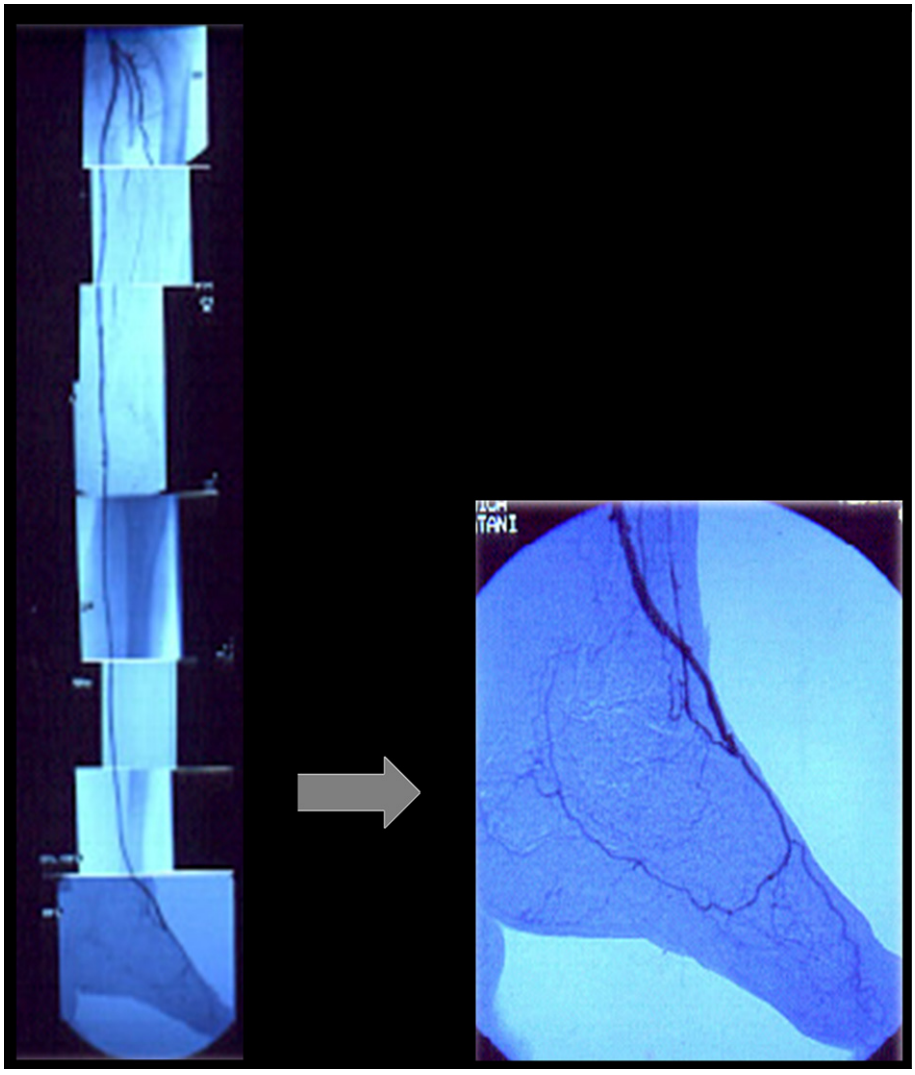


Figure 2 Long graft bypass Femoral Common — Dorsalis pedis with greater saphenous vein.

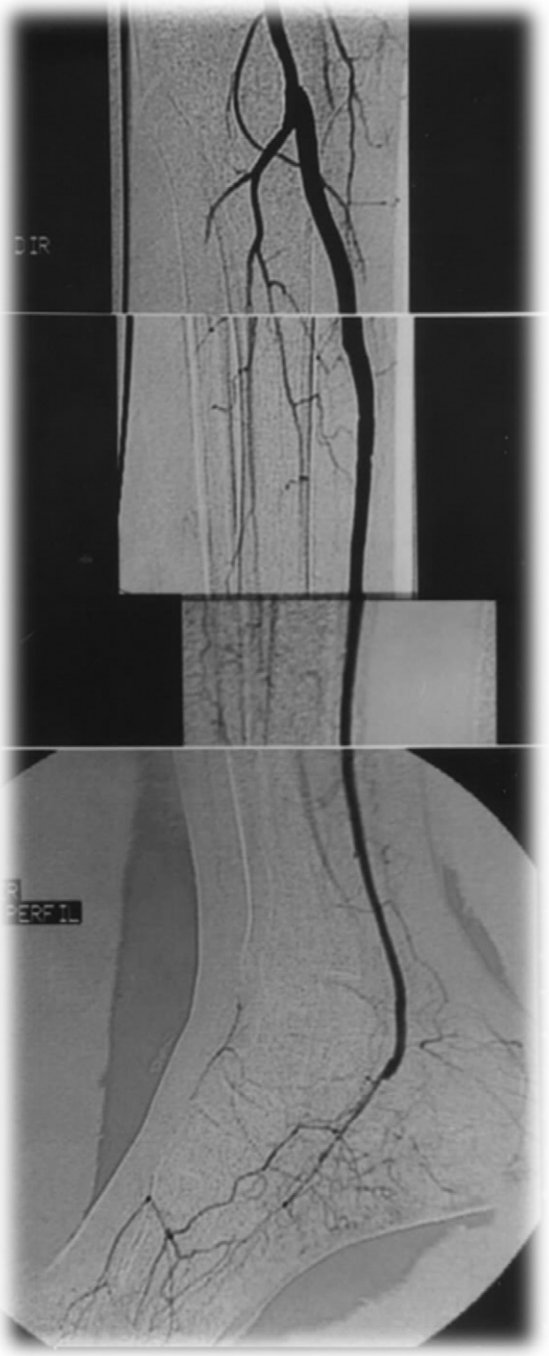
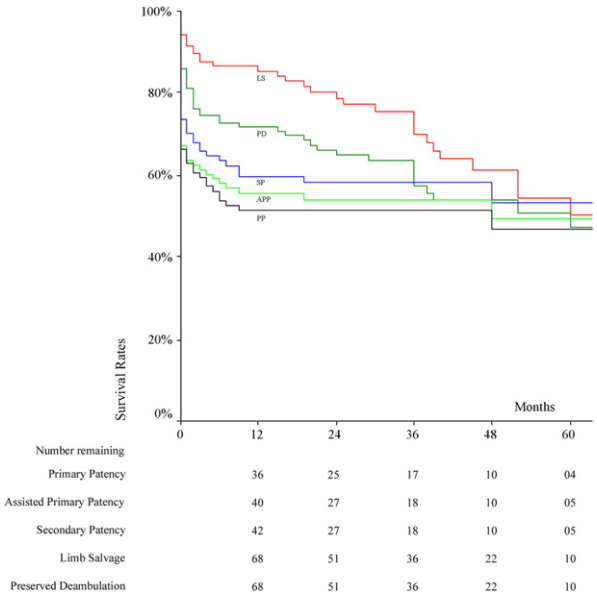


Figure 3 Short-graft bypass below-knee popliteal — lateral plantar with basilic vein.

devalvulated veins.[22] The advantage of this approach is that it enables use of the best vein segments and the vein is harvested by staggered incisions, in contrast to the *in-situ* technique. In short bypasses, the vein can be used in the reversed position, especially considering that the saphenous vein is narrower at the knee than in the lower third of the leg.

We found no statistical difference in the results of long and short bypasses. Short bypasses were preferred when possible and the best distal point on the donor artery for the proximal anastomosis was identified, as also preferred in previous



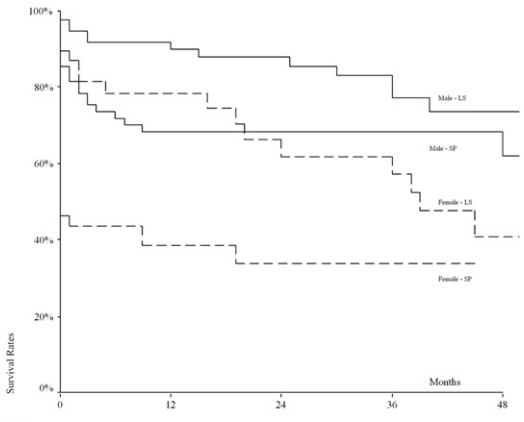
Number remaining					
Primary Patency	36	25	17	10	04
Assisted Primary Patency	40	27	18	10	05
Secondary Patency	42	27	18	10	05
Limb Salvage	68	51	36	22	10
Preserved Deambulation	68	51	36	22	10

Graphic 1 Cumulative function rates of inframalleolar bypass graft surgery (Kaplan—Meier). PP, primary patency; APP, assisted primary patency; SP, secondary patency; PD, preserved deambulation; LS, limb salvage.

studies.[23—25] This approach avoids the dissection of the inguinal region and allows the use of the best vein segment.

Although we used a few alternative grafts in this series ($n = 19$),[26] better results were achieved with a non-composite saphenous vein ($n = 103$).

Even though surgeons carefully investigate graft patency during follow-up, the relief of pain, trophic lesion cicatrisation and limb salvage are the most important targets. If CLI disappears and if there is time for a rich collateral circulation to form, the extremity is viable even with eventual graft occlusion. We have found this condition at the 3-year analysis, when the rate of limb salvage (70.5%) was greater than the cumulative graft patency (57.8%). After 5 years, this phenomenon was not observed (50.8%



Number Remaining				
Male - Secondary Patency	33	22	15	10
Male - Limb Salvage	48	37	24	17
Female - Secondary Patency	08	05	03	00
Female - Limb Salvage	20	14	12	05

Graphic 2 Forty-eight month cumulative rates of secondary patency (SP) and limb salvage (LS) in males and females (Kaplan—Meier; Log-Rank — $P < 0.01$ for SP and $P = 0.05$ for LS).

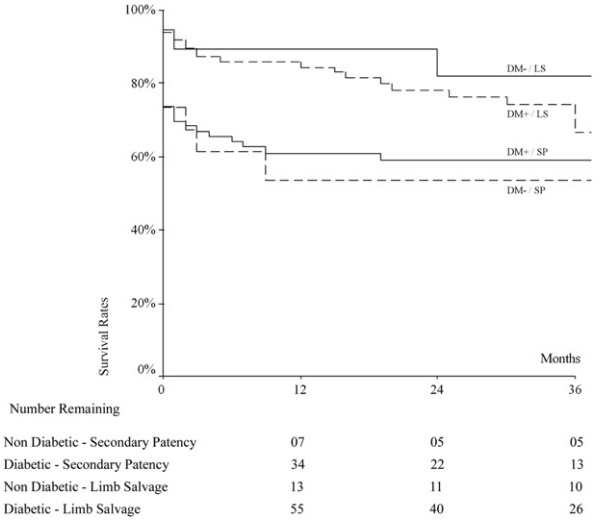
Table 5 Univariate analysis of inframalleolar bypass graft surgery outcomes (log-rank).

Variable		Final Patency				Limb Salvage			
		N	Failure per 100 individuals/mo	Rate of events	*P*	*N*	Failure per 100 individuals/mo	Rate of events	*P*
Age	≤69	59	3.847	0.84	0.49	59	0.908	0.62	0.22
	>69	63	4.568	1		63	1.466	1	
Sex	Female	39	3.483	0.79	<0.001	39	1.785	1	0.005
	Male	83	4.397	1		83	0.977	0.55	
Hypertension	No	34	1.681	0.49	0.15	34	0.927	0.74	0.47
	Yes	88	3.425	1		88	1.259	1	
Diabetes	No	19	2.597	0.9	0.85	19	0.814	0.65	0.41
	Yes	103	2.876	1		103	1.255	1	
Congestive heart disease	No	96	2.937	1	0.83	96	1.065	0.71	0.38
	Yes	16	2.941	1		16	1.496	1	
Smoking	No	75	3.468	1	0.91	75	1.283	1	0.56
	Yes	39	2.255	0.65		39	0.996	0.78	
Distal anastomosis	Dorsalis pedis	76	2.679	0.88	0.34	76	1.199	1	0.84
	Others	46	3.031	1		46	1.126	0.94	
Substitute	GVS	19	4.184	1	0.29	19	1.073	0.90	0.86
	Others	103	2.610	0.62		103	1.188	1	
Graft extension extension	Short	76	2.598	0.78	0.87	76	1.045	0.73	0.50
	Long	46	3.327	1		46	1.430	1	

GSV, greater saphenous vein.

limb salvage and 52.6% graft patency) but we must consider that infections in the diabetic foot are an important cause of limb loss. This fact was noted during analysis of limb salvage in the non-diabetic group compared with the diabetic group (Graphic 3).[27] Because the rate of limb salvage was satisfactory, the preserved deambulation rate was 47.1% at 5 years and the survival rate in the same period was only 38.4%. Our results are satisfactory and similar to those of the large series published by Pomposelli et al.[11]

Percutaneous angioplasty is currently used for the treatment of infrapopliteal arteries, mainly in short lesions, classified as TASC A, B or even C. In TASC D lesions, the main



Graphic 3 Thirty-six month cumulative rates of secondary patency (SP) and limb salvage (LS) in diabetic (DM+) and non-diabetic (DM−) patients (Kaplan−Meier).

treatment is surgical bypass, as previously reported by Giles et al.,[28] who found low rates of primary patency and limb salvage in extensive arterial disease over a period of 2 years. Our indications were based on the TASC classification; consequently, for TASC C and D lesions, bypass is performed in patients with a favourable surgical risk. In patients unsuitable for bypass (high surgical risk, lack of conduits or good arteries for use in anastomosis), the option is endovascular treatment. In many centres, the endovascular approach is recommended as a primary approach to critical limb ischaemia; we also consider that surgical training in performing inframalleolar bypass is important to achieve limb salvage in situations of endovascular failure.

Some bypasses were implanted in the vicariate branches of the foot arteries (lateral and medial plantar, tarsal lateral), with an acceptable limb salvage rate at 3 years (77.0%). The use of these branches for outflow is justified and should be considered in patients for whom conventional surgery is not possible, as the last chance for limb salvage.[29–33]

Although distal anastomosis is performed close to trophic injuries in autogenous grafts for foot arteries, the rate of infection observed in this situation (2.4%) was equivalent to that associated with infrainguinal autogenous grafts.

The clinical status of surgical patients with CLI could be reflected in the high rate of surgical mortality (13%).

Conclusion

In the present series of patients, bypasses of arteries in the foot presented satisfactory medium- and long-term rates of patency and limb salvage, demonstrating the beneficial use of these arteries in revascularisation for CLI. The greatest associated risk factor was diabetes mellitus, which is

related to the preservation of foot arteries from atherosclerotic disease. The female sex was associated with worse results for cumulative patency and limb salvage. The vicariate branches of the foot arteries could be another option in run-off bypass.

Conflict of interest

None.

Funding

None.

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